

# PSJ3

## Exhibit 320

## PROJECT PLAN – SOM

### Meet with Malinckrodt – February 2013

- Discuss our present SOM program in place
- Inquire information on their program ie. the type of program they have in place.
  - \*What metrics do they use in evaluating whether an order is deemed suspicious (excessive quantity), have they rejected and reported to DEA any customer orders that were excessive quantity, what unit of measure do they use (monthly dosage units, sku's?), are drug items looked at separately or are drug families grouped together?

### Complete the questionnaire we currently have on file for customer visits

### Develop/complete letter to be sent to the **Big 4 wholesalers** inquiring about their SOM program.

- Send letter to wholesalers with questionnaire
- Setup face to face meeting with the sites responsible for managing the SOM program
- Discuss the program Teva has in place and what Teva expects from our customers. (SOM program in place, have excessive order quantities deemed outside the customer's ordering pattern investigated, documented and/or reported to DEA as suspicious, have they visited their customers for increased product purchases, what due diligence have they conducted on their own customers?)
- Recommend best practices of any customer not having a sufficient SOM program and follow up with those customers 6 months later?

### Develop/complete letter to be sent to the **Retail Pharmacy Chains and secondary wholesalers.**

- Send letter to corporate Retail Pharmacy locations and secondary wholesalers inquiring about their SOM program in place.
- Set up face to face visits where the SOM program resides.
- Discuss the program Teva has in place and what Teva expects from our customers. (SOM program in place, have excessive order quantities deemed outside the customer's ordering pattern investigated, documented and/or reported to DEA as suspicious, have they visited their customers for increased product purchases, what due diligence (license verifications) have they conducted on their own customers?)
- Recommend best practices of any customer not having a sufficient SOM program and follow up with those customers 6 months later?

### SOP's – Suspicious Order Monitoring

- New customers- Customer Service will verify all licenses to include DEA, pharmacy, pharmacist, wholesaler, controlled substances that they are valid, active and in good standing. Notify Diversion Operations of any new customers so that a site visit can be conducted.
- Customer orders uploaded to “SORDS” that have exceeded one or more of the UCL’s (Upper Control Limits) whether it is daily, monthly, or quarterly.
- Each order is to be investigated as to why the order has exceeded one or more of the UPL’s to include researching the customer’s prior purchasing history.
- If the customer’s order significantly exceeds the prior 12 months purchase history and no further information is known, contact with Customer Service is to be made and Customer Service is to contact the customer to determine the reason for the order that is outside their normal purchasing pattern.
- Customer Service will notate any communication with the customer as to the reason for the order above their purchase history and forward that information to the Diversion Investigator (D.I) and Diversion Manager (D.M).
- If the response is acceptable by the D.I. or D.M. they will input the notes received from Customer Service into the comments section of the order release field and release the order.
- If response received from customer is not acceptable (ie..customer ordering large amounts of Oxycodone to beat a price increase that will occur next week) that order should be cancelled and reported to DEA as suspicious. **According to 21 C.F.R. Section 1301.74, “Suspicious orders include orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency”.**

### Customer Service Role in SOM

- Customer Service is to not communicate to the customer what their UPL’s are as this will defeat the purpose of the SOM program.
- Customer Service will not cut or adjust a customer’s order so that the order will fail to hit the SOM program as this will circumvent the SOM program.
- If a customer’s order is **rejected** by Diversion Operations, the customer service rep will call the customer back advising that their order has been reviewed and is outside their normal purchase pattern and has been rejected. The customer service

rep may tell the customer that they can order “up to x amount” without divulging the “upper control limit” for the particular drug.

#### SORDS Improvements

- Grouping of drug items into drug families.

#### Evaluation of Chargeback Data